IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

ROBERT DANIEL TAYLOR,

Plaintiff,

v.

LEANNE POLHILL; RANDY ELLSWORTH; ROBERT PICKARD, MD; JOHN FISCHER; DOUGLAS MOORE; PAMELA DECHMEROWSKI; MARIA HERNANDEZ; and THOMAS HOLLERN; each solely in their official capacities as Members of the Florida Board of Hearing Aid Specialists; CELESTE PHILIP, MD, MPH, solely in her official capacity Secretary of the Florida Board of Health,

Defendants.

Case No. 6:18-cv-00613-GAP-DCI

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

For over 30 years, Plaintiff Robert Daniel (Dan) Taylor has earned his livelihood by selling hearing aids in Florida as a licensed hearing aid specialist. He declined to renew his license last year because he believes the state's requirement that he use antiquated procedures and equipment in the sale of hearing aids unnecessarily burdens his business and prevents him from rendering the best service to his customers. That requirement is also preempted by federal law.

Recently, the Florida Board of Hearing Aid Specialists sent Taylor a letter notifying him that it had opened an investigation into his business activities for the practice of dispensing hearing aids without a license. *See* Decl. of Dan Taylor, Ex. 1. Faced with potential fines and penalties, and now deprived of his livelihood, Taylor seeks a preliminary injunction to enjoin enforcement of Florida's hearing aid specialist licensing statute against him while he challenges it in court.

FACTUAL BACKGROUND

Federal Regulation of Hearing Aid Devices

Congress enacted the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetics Act to regulate the sale and ensure the safety of various medical devices. 21 U.S.C. § 321(h). The Amendments give the FDA authority over three classes of medical devices. *Id.* Most hearing aids are Class I devices, which are recognized as posing little concern to public health. 21 C.F.R. § 874.3300; 21 U.S.C. § 360c. Other Class I devices include dental floss and tongue depressors. 21 C.F.R. § 872.6390; 21 C.F.R. § 880.6230. Some hearing aids are considered Class II devices, which likewise present little risk to

public health, but require premarket approval by the agency. 21 C.F.R. § 874.3300. Other Class II medical devices include heating pads. 21 C.F.R. § 890.5740.

Approximately 15% of American adults—or 37.5-million people—report some trouble hearing. *See* U.S. Dep't of Health and Human Services, National Inst. on Deafness and Other Communication Disorders, *Quick Statistics About Hearing*.[1] Yet the FDA estimates that only 1/5 of people who could benefit from hearing aids actually seek them. *See* FDA News Release, *FDA Takes Steps to Improve Hearing Aid Accessibility*. [2] This is, in part, because onerous and outdated regulations limit who may sell hearing aids, thereby decreasing the devices' availability and increasing their cost. *Id.* Recognizing that unnecessary and anticompetitive regulations reduce access to hearing aids, the MDA explicitly preempts any state requirements that are "different from, or in addition to" federal regulations, and that relate to the "safety or effectiveness" of the device. 21 U.S.C. § 360k(a).

The FDA has promulgated comprehensive rules regulating the conditions of sale of hearing aids, including a requirement that hearing aid devices carry specific labeling and that manufacturers provide a brochure that includes product information. *See* 21 C.F.R. § 801.420(b)-(c). The rules also require hearing aid dispensers to be aware of eight "red flags" and, if a dispenser learns about one of these flags by observation or by other information, he must "advise a prospective hearing aid user to consult promptly with a licensed physician" prior to the sale of a hearing aid. 21 C.F.R. § 801.420

[1] https://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing.
[2] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm532005.htm.

Federal rules further prohibit dispensers from selling a hearing aid unless the prospective user has obtained a medical evaluation within the prior six months and been deemed a candidate for a hearing aid, or, if the user is over 18, she waives the medical evaluation. 21 C.F.R. § 801.421(a). Federal regulations also require dispensers to retain a copy of either the waiver or the physician's written statement. 21 C.F.R. § 801.421(d). However, the FDA issued guidance in December 2016, stating that it "does not intend to enforce certain conditions for sale of hearing aids that are required per FDA regulation," including the mandatory medical evaluation or recordkeeping requirement for persons over 18, given that those requirements discourage people from getting hearing aids without providing any material health or safety benefit. FDA, *Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids, Florida's Regulation of Hearing Aid Devices*.[3]

Florida's Regulations of Hearing Aid Devices

Florida's hearing aid specialist licensing law requires anyone who dispenses hearing aids to obtain a license. Fla. Stat. § 484.053. Obtaining a hearing aid specialist license is onerous, requiring six months of training, license fees, and successful examination by the Florida Board of Health. The license must be maintained by continuing education and fees. Fla. Stat. §§ 484.0445, 484.0447, 484.045, 484.047.

The licensing law also imposes conditions of sale on licensees—many of which directly conflict with the federal regulations. Florida requires all licensed hearing aid

[3] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM531995.pdf.

specialists to conduct an audiological exam and fitting prior to any sale using the state's mandated protocols. Fla. Stat. § 484.0501. Specifically, specialists must conduct an audiological exam measuring pure tone air-conduction thresholds, test speech reception thresholds, determine speech discrimination scores, and discern the most comfortable and uncomfortable loudness levels. *Id.* They are also required to conduct an otoscopy to inspect the ear canal, to interrogate the consumer about recent health history, and to notify the prospective purchaser of the benefits of particular hearing aid technology. *Id.* Selling a hearing aid without a license or without following the specified minimum procedures is a third degree felony.

Moreover, all minimum procedures must be conducted using particular equipment. *Id.* Florida law requires that testing be done using a wide range audiometer that meets the specifications of the American National Standards Institute in a specially constructed testing room certified by the Florida Department of Health or by an agent approved by the Department. *Id.*

Neither federal law nor FDA regulations require audiological testing or a fitting of any kind prior to the sale of hearing aids, nor that it be done with any particular kind of equipment. In fact, FDA has determined that mandatory audiological exams are "not necessary," drive up the cost of hearing aids, and are preempted by federal law. 45 Fed. Reg. 67,326-67,329 (Oct. 10, 1980).

Florida law also prohibits all sales and distribution of hearing aids through the mail, thereby barring mail-order or internet sales of hearing aid devices to Florida consumers. *See* Fla. Stat. § 484.054. Selling a hearing aid by mail order in violation of Florida law is a

second-degree misdemeanor. Taylor contends that the requirement that sellers of hearing aids obtain a license is preempted because the licensing scheme imposes mandatory conditions of sale contrary to MDA's preemption statement: first, it requires licensees to administer a pre-sale audiological exam and fitting using particular procedures and equipment; second, it bans mail-order sales. *See* Complaint ¶¶ 87-104.

Plaintiff Dan Taylor

Dan Taylor is an entrepreneur who was a licensed Hearing Aid Specialist for more than 30 years between 1984 and February 2017. Declaration of Dan Taylor ¶ 2. After dispensing hearing aids as an employee of various hearing aid retailers, and working as an equipment representative, Taylor opened his own store in 1992. *Id.* ¶ 3. In all of his years as a licensed Hearing Aid Specialist, Dan was never disciplined or sanctioned by the Board of Hearing Aid Specialists or any other administrative or law enforcement agency due to any consumer complaint. *Id.* ¶ 4.

Modern hearing aids of the type sold by Taylor allow for fitting to be done using *in situ* audiometric testing—that is, testing using the hearing aid device itself rather than audiometric equipment in a sound-controlled environment. *Id.* ¶ 6. Modern firmware and software built into the devices allows for the fitting of the hearing aid to be performed at standards that are as good or superior to the minimum procedures and equipment mandated by the Florida laws challenged herein. *Id*. *In situ* audiometric testing is less time-consuming and more convenient for many consumers than the minimum procedures and equipment mandated by Defendants, and results in equal or greater consumer satisfaction than older methods of "fitting." *Id.* ¶¶ 6-7. The effective selection and fitting of hearing aids today

can even be done using personal computers and smartphones with minimal, nonmedical training; some hearing aid models are designed to allow consumers themselves to fit their hearing aids for comfort using smartphone applications or a PC with "Bluetooth" technology. *Id.* The more intrusive and time-consuming fitting procedures mandated by Florida law tend to dissuade consumers from seeking information or engaging in the process of selecting a hearing aid. *Id.* ¶ 7.

Taylor wants to provide the best service that he can to consumers, and to effectively serve as many consumers as feasible. *Id.* ¶ 8. For this reason, he does not want to conduct hearing aid fitting according to the procedures mandated by Florida law as a condition of selling the devices, and instead wants to conduct his business using superior software and hardware available with modern hearing aids. *Id.* ¶ 8. In 2017, after considering FDA guidance and reading about hearing aid licensing-related lawsuits in other states, Taylor decided not to renew his Hearing Aid Specialists license and to practice his occupation following federal standards and regulations. *Id.* ¶ 5.

Taylor recently received a letter from the Florida Board of Hearing Aid Specialists notifying him that the Board was opening an investigation into his business activities for dispensing hearing aids without a license. *Id.* ¶ 9. Taylor brought suit under 42 U.S.C. § 1983 to vindicate his right to earn a living free of Florida's preempted law, and brings this motion to enjoin enforcement of the law, including any enforcement actions against him, during the pendency of the lawsuit.

LEGAL STANDARD

To succeed on a motion for a preliminary injunction, movants must show: (1) a likelihood of success on the merits; (2) that they are at risk of suffering irreparable harm if preliminary relief is denied; (3) that their potential injury outweighs the potential harm to the defendant; and (4) that granting injunctive relief does not disserve the public interest. *See, e.g.*, *Odebrecht Constr., Inc. v. Sec'y, Fla. Dep't of Transp.*, 715 F.3d 1268, 1287 (11th Cir. 2013). Taylor easily satisfies all four factors.

SUMMARY OF THE ARGUMENT

Taylor meets the four factors necessary to obtain a preliminary injunction. First, he is likely to succeed on the merits of his claim that Florida's hearing aid specialist licensing law is preempted. The MDA expressly preempts state laws that are "different from" or "in addition to" federal requirements, and which "relate to the safety or effectiveness of the device." 21 U.S.C. § 360k(a). Florida's hearing aid specialist licensing law is "different from" and "in addition to" the FDA's regulations because it requires a presale audiological exam—which is not required by the FDA—and because it bans mail-order sales—which the FDA permits. Indeed, because these requirements reduce access to hearing aids without providing any health or safety benefit, the FDA has determined that they "would interfere with the execution and accomplishment of the objectives of FDA's hearing aid regulation" and are preempted. 45 Fed. Reg. 67,327.

Florida's hearing aid specialist licensing law "relate[s] to the safety or effectiveness of the device" because it is intended to prevent "physical and economic harm" and to ensure that aid actually enhances the purchaser's hearing. Fla. Stat. § 484.0401. Several courts

have therefore held that licensing regimes like Florida's are preempted. *See, e.g.*, *Missouri Bd. of Exam'rs for Hearing Instrument Specialists v. Hearing Help Express, Inc.*, 447 F.3d 1033, 1036 (8th Cir. 2006); *METX, LLC v. Wal-Mart Stores Texas, LLC*, 62 F. Supp. 3d 569, 584 (E.D. Tex. 2014); *Mass. v. Hayes*, 691 F.2d 57, 63 (1st Cir. 1982); *New Jersey Guild of Hearing Aid Dispensers v. Long*, 384 A.2d 795, 812 (N.J. 1978).

Second, Taylor will suffer irreparable harm absent an injunction. Because Taylor believes that Florida's licensing law mandates outdated and unnecessary procedures, and because he believes those requirements are preempted, he has chosen not to renew his hearing aid specialist license. Now, he has to give up his primary source of revenue in order to avoid prosecution for the unlicensed practice of hearing aid sales. *See Odebrecht Constr.*, 715 F.3d at 1288 (loss of revenue is irreparable harm). Indeed, Defendants have warned him that they are looking into his business activities and he faces potential fines and penalties unless Defendants are enjoined from enforcing the licensing law. *See also ABC Charters, Inc. v. Bronson*, 591 F. Supp. 2d 1272 (S.D. Fla. 2008) (potential prosecution is irreparable harm).

Third, the potential harm to Taylor outweighs any potential harm to Defendants or the public. The government is not harmed by being prevented from enforcing an unconstitutional law. *KH Outdoor, LLC v. City of Trussville*, 458 F.3d 1261, 1272 (11th Cir. 2006). And if the state is enjoined from enforcing its law against Taylor, the public will be adequately protected by federal law, which already restricts the sale of hearing aids in a manner the FDA has deemed necessary to protect the public.

Last, granting the injunction is in the public interest. The public has a substantial interest in determining the constitutionality of a challenged law, *ABC Charters*, 591 F. Supp. 2d at 1310, and an injunction will allow Taylor to seek judicial resolution of his claims.

ARGUMENT

I

TAYLOR IS LIKELY TO SUCCEED ON THE MERITS OF HIS CLAIMS

Taylor is likely to succeed on the merits of his claims because the MDA expressly preempts Florida's hearing aid licensing laws, which require presale testing and fitting and ban mail-order hearing aid sales. The MDA expressly preempts state regulations that are "different from, or in addition to" the federal rules and that "relate[] to the safety or effectiveness" of the device. 21 U.S.C. § 360k(a). Florida's licensing statutes are "different from" and "in addition to" those rules because they require a presale audiological exam using specific minimum procedures prior to any sale and because they prohibit mail-order sales of hearing aid devices. By contrast, the FDA permits the sale of hearing aids without any presale audiological exam and deems such state-imposed requirements to be preempted by the MDA. *See* 45 Fed. Reg. 67,326-67,328.

Notably, the FDA has determined that "[t]here is no evidence that audiological evaluation reduces or eliminates any risk to health presented by a hearing aid," and therefore the federal rules do not include an exam as a mandatory condition of sale. Instead, the FDA has determined that state-mandated audiological exams "would interfere with the execution and accomplishment of the objectives of FDA's hearing aid regulation," are "in

addition to" those requirements, and are therefore preempted. 45 Fed. Reg. 67,327. *See also* 45 Fed. Reg. 67,328 ("Because the FDA hearing aid regulation preempts State laws requiring audiological evaluation, the States may not require, as a condition to the purchase of a hearing aid, that the prospective purchaser receive an audiological evaluation."). FDA has repeatedly denied requests to be exempted from preemption from those states that require mandatory audiological sales. *Id.*

Moreover, FDA permits mail-order sales so long as sellers abide by the federally mandated conditions of sale. Both Florida's mandated procedures and ban on mail-order sales relate to the "safety" and "effectiveness" of the device because they are designed to ensure that hearing aids function safely and properly. 45 Fed. Reg. 67,326-67,327. They are therefore preempted. *See, e.g.*, *Missouri Bd. of Exam'rs for Hearing Instrument Specialists*, 447 F.3d at 1036; *METX, LLC*, 62 F. Supp. 3d 569 at 584; *Hayes*, 691 F.2d at 63; *New Jersey Guild of Hearing Aid Dispensers*, 384 A.2d at 812.

A. The MDA Expressly Preempts State and Local Laws

Under the Supremacy Clause, federal laws and regulations are the "Supreme law of the land," and any state law that interferes with or is contrary to federal regulations is preempted. U.S. Const. art. VI, cl. 2; *ABC Charters*, 591 F. Supp. 2d 1272. Preemption may be either express or implied. Preemption is express when Congress uses clear preemptive language. *Odebrecht Constr.*, 715 F.3d at 1274. Under express preemption, Congress's language governs and "there is no need to infer congressional intent." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992). Preemption is implied where the statutory

language indicates Congress's intent to occupy the field, or where state regulation conflicts with or frustrates federal law. *Id.*

The MDA includes an express preemption clause. Its language clearly and unambiguously preempts any state law pertaining to hearing aid devices:

1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter. 21 U.S.C. § 360k(a).

In *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008), the Supreme Court held that Section 360k(a) conveys Congress's intent to expressly preempt state laws regulating the sale of medical devices. Because Congress used clear language in the preemption statement, a court need only compare the challenged statute to the statutory language. *Id.*; *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001) (MDA includes express preemption statement).

Federal courts agree that the MDA expressly preempts state hearing aid regulations. In *Missouri Bd. of Exam'rs for Hearing Instrument Specialists*, 447 F.3d 1033, the Eighth Circuit held that the MDA expressly preempted state law, and the specific preemption language determined whether a given law was preempted and void. *See Hayes*, 691 F.2d 57 (MDA "expressly preempt[s]" state law governing the sale of hearing aids); *METX*, 62 F. Supp. 3d 569 (same).

These judicial opinions are consistent with the FDA's own opinion. According to the FDA, the MDA "expressly preempt[s]" state laws regulating hearing aid sales because Section 360k expresses Congress's "purposes and objectives with respect to the preemption of State and local medical device requirements." 45 Fed. Reg. 67,327; *see also id.* (the "test of implied Federal preemption . . . does not apply"). The FDA noted that an implied preemption standard would render Congress's preemption statement meaningless, because it would preempt only those laws that conflict with the MDA, where the statute specifically preempts any laws that are "different from or in addition to" the MDA. Reviewing Florida's statutes according to an implied preemption standard would therefore be contrary to Congress's intent.

Because the MDA's clear language explicitly preempts state law, it is necessary to determine whether Florida's hearing aid dispenser laws are "different from, or in addition to" the Act and whether they "relate[] to the safety or effectiveness of the device." *See Cipollone*, 505 U.S. at 517 (Where Congress has included a preemption provision, preemption is "governed entirely by the express language.").

B. Florida's Hearing Aid Licensing Law Is "Different From" and "In Addition to" the MDA

Florida law requires that all persons wishing to sell hearing aids first obtain a hearing aid specialist license. Fla. Stat. § 484.053. That licensure process requires an applicant to undergo training, pay fees, and pass an examination. Fla. Stat. § 484.045. Once licensed, it requires hearing aid dispensers to follow mandated conditions of sale, including administering a presale audiological exam and fitting using state-approved procedures and equipment. Fla. Stat. § 484.0501. All procedures must be conducted in a room "certified

by the department," unless specifically requested and waived by the client. Fla. Stat. § 484.0501(6).

All of these conditions of sale are "different from and in addition to" the conditions of sale imposed by federal regulations. 45 Fed. Reg. 67,327. While the federal rules impose various conditions on the sale of hearing aids, they do not require a presale audiological exam. In fact, FDA has concluded that such a requirement "is not necessary to provide reasonable assurance of the safety or effectiveness of hearing aids." 45 Fed. Reg. 67,329. Instead, these burdens "increase the cost of" and reduce access to hearing aid devices, "without providing any conclusive assurance that the patient would benefit." *Id.* Thus, while FDA permits prospective purchasers to commission an exam and fitting if they'd like one, it does not require sellers of hearing aids to engage in these practices. The FDA has determined that state-mandated exams are "in addition to the Federal requirements applicable to hearing aids," and therefore preempted. 45 Fed. Reg. 67,327; *cf. McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005) (state law preempted by MDA where a person "could be held liable under the state law without having violated the federal law").

In *Missouri Bd. of Exam'rs for Hearing Instrument Specialists*, 447 F.3d at 1036, the Eighth Circuit held that Missouri's mandatory presale audiological exam was "different from" and "in addition to" federal regulations and therefore preempted by the MDA. The state argued that such a requirement was not preempted because it "deal[t] only with fitting and testing," which is "not regulated by the MDA." The court rejected that argument because the statute fell squarely within the express preemption statement of the MDA. The state's argument was irrelevant under an express preemption analysis.

Likewise in *METX*, 62 F. Supp. 3d 569, the district court held that Texas's licensing law was preempted because it required, among other things, that licensees perform a presale audiological exam. Such a requirement was "additional" to federal law because it was not one of the conditions of sale required under FDA regulations governing hearing aids. *See also New Jersey Guild of Hearing Aid Dispensers*, 384 A.2d at 812 (mandated audiological exam was "in addition to" federal regulations because "a dispenser would be forced to comply with two variant rules prior to dispensing a hearing aid.").

The Fifth Circuit[4] has held that an element of Florida's licensing scheme was not preempted in *Smith v. Pingree*, 651 F.2d 1021, 1026 (5th Cir. 1981), but only because the court analyzed the statute under an implied preemption standard. There, the plaintiffs challenged the requirement that testing occur within certified testing rooms. The court reasoned that "where Congress has chosen to 'occupy' a field, but has not undertaken to regulate every aspect of that area, the states have the implied reservation of power to fill out the scheme." *Id*. According to the court, because the MDA did not address hearing aid fitting, the state was free to require that fitting occur in Commission-approved rooms. However, the decision in *Pingree* has been negated by subsequent Supreme Court decisions that require preemption claims under the MDA to be reviewed according to *express* preemption standards. *See, e.g.*, *Riegel*, 552 U.S. 312.

The Eighth Circuit, First Circuit, Texas district court, and New Jersey Supreme Court have also subsequently analyzed state laws relating to hearing aid fitting under an

[4] This case was decided prior to the establishment of the Eleventh Circuit, when the Fifth Circuit had jurisdiction over the territory now governed by the Eleventh Circuit. Thus, it is properly considered Eleventh Circuit precedent.

express preemption standard and ruled that the laws were preempted. Those cases, following the U.S. Supreme Court, hold that the MDA expressly preempts state statutes that are "different from or in addition to" federal regulations, even if the federal government has not undertaken to regulate every aspect of the field. *See, e.g.*, *Missouri Bd. of Exam'rs for Hearing Instrument Specialists*, 447 F.3d at 1036; *METX*, 62 F. Supp. 3d at 584; *Hayes*, 691 F.2d at 63; *New Jersey Guild of Hearing Aid Dispensers*, 384 A.2d at 812. Had the Fifth Circuit analyzed Florida's law under express preemption as is now required pursuant to subsequent Supreme Court precedent, the case likely would have come out differently.

In sum, because Florida imposes an additional condition of sale on hearing aid dispensers, its licensing law falls under the first preemption prong of 21 U.S.C. § 360k(a).

C. Florida's Hearing Aid Licensing Law Is "Related to the Safety and Effectiveness of the Device"

Florida's requirement that fitters administer a presale audiological exam using specified procedures and equipment also fits under the second preemption prong because it relates to the safety and effectiveness of hearing aids. The statute states that its purpose is to "protect the public from physical and economic harm" because "a poorly selected or fitted hearing aid not only will give little satisfaction but may interfere with hearing ability." Fla. Stat. § 484.0401. It therefore "deems it necessary in the interest of the public health, safety, and welfare to regulate the dispensing of hearing aids in this state." *Id*. In other words, the presale audiological exam is not, for example, a pricing regulation. The purpose of the regulation is to ensure safety because it is designed to prevent "harm," and

its purpose is to ensure effectiveness because it is designed to ensure the aid does not "interfere with hearing ability."

The FDA has determined that mandatory audiological evaluations "relate[] to the safety or effectiveness of hearing aids" because they are "intended to ensure that the purchaser is fitted properly with a hearing aid that will benefit his or her hearing ability." 45 Fed. Reg. 67,327. Every court that has considered the question agrees. *Missouri Bd. of Exam'rs for Hearing Instrument Specialists*, 447 F.3d at 1036; *METX*, 62 F. Supp. 3d at 584; *Hayes*, 691 F.2d at 63; *New Jersey Guild of Hearing Aid Dispensers*, 384 A.2d at 812. It therefore meets the criteria in 21 U.S.C. § 360k(a)(2).

D. Florida's Ban on Mail-Order Hearing Aids Is "Different From" and "In Addition to" the MDA

Because hearing aids can be expensive, purchasing hearing aids through the mail can offer a less costly means of obtaining hearing help. Given increases in technology, many find mail-order hearing aids to be just as effective as aids purchased in a shop. Taylor also intends to sell hearing aids by mail. But Florida bans the sale of hearing aids through the mail, imposing fines and even threatening jail time for mail-order sales. Fla. Stat. § 484.054.

By contrast, the MDA permits sales of hearing aids through the mail so long as prospective purchasers undergo (or waive) a medical exam, and so long as the hearing aids are labeled and packaged with certain product information. It is notable that FDA has recently moved to lessen even those burdens by stating that it would no longer enforce the mandatory medical exam, and it did so on the basis that such exams needlessly increase

costs without protecting consumer safety. Florida does not just impose burdens on mail order sales—it outright bans them, which directly contradicts the federal regulations.

In *Missouri Bd. of Exam'rs for Hearing Instrument Specialists*, 447 F.3d 1033, the state prohibited mail order sales without prior fitting and testing by a licensed specialist. The Eighth Circuit held that the law was "different from, or in addition to" federal regulations because it made audiological exams mandatory before a mail order sale. Florida goes one step further prohibits mail order sales with or without an exam. That is not just different "in addition to" federal regulation, is it directly contrary to it, because federal rules permits such sales. Florida's ban is therefore preempted.

E. Florida's Ban on Mail-Order Hearing Aids Relates to the "Safety and Effectiveness of the Device"

Like the state's mandatory conditions on sale, Florida's ban on mail-order sales is related to the safety and effectiveness because it is meant to protect consumer health and ensure that hearing aids actually help consumers. *See* Fla. Stat. § 484.0401.

F. Florida's Hearing Aid Specialist Licensing Law Is Not Saved from Preemption

The FDA has promulgated a rule that exempts some state statutes from preemption, but that clause does not apply here. Specifically, the rule states that the MDA does not preempt "State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine [. . .] or any other of the healing arts or allied medical sciences or related professions or occupations that administer, dispense, or sell devices." 21 C.F.R. § 808.1(d)(3). However, "[i]f there is a conflict between such restrictions and State or local requirements, the Federal regulations shall

prevail." *Id.* That means that while federal regulation is not generally meant to preempt licensing, registration, certification or other requirements that relate to ensuring medical professionals are qualified to do their jobs, it will preempt even licensing laws that impose additional conditions of sale that conflict with the MDA.

In *METX*, 62 F. Supp. 3d 569, licensed hearing aid sellers complained that large retailers were selling hearing aids in Texas without a license and without administering presale exams mandated by the state's licensing statute. The district court rejected the challenge and struck down the law because it held that the licensing requirement and mandatory exams were preempted. After holding that the statute was "different from" and "in addition to" federal regulations, and that it related to the "safety and effectiveness of the device," the court rejected the argument that the licensing regime was saved from preemption by 21 C.F.R. § 808.1(d)(3). It reasoned that "licensure is only exempted from preemption to the extent it does not impose requirements applicable to a device different from, or in addition to specific FDA requirements." *METX*, 62 F. Supp. 3d 580. In other words, the state could not bootstrap its way out of preemption by embedding its preempted regulations within a "licensing" statute.

Similarly here, Taylor does not challenge those licensing requirements related to ensuring the competency of hearing aid fitters. Instead, he challenges the licensing requirements that impose conditions of sale that are "different from" and "in addition to" federal law and which relate to the "safety and effectiveness" of hearing aids. The savings clause therefore does not apply.

II

TAYLOR WILL SUFFER IRREPARABLE HARM ABSENT AN INJUNCTION

If Defendants are not enjoined from enforcing Florida's hearing aid specialist licensing statute, Taylor will suffer harm in the form of lost business profits and potential prosecution. Taylor Decl. at 10. Both injuries are actual and imminent, and are irreparable because there is no adequate remedy at law. *See Odebrecht Constr.*, 715 F.3d at 1288. Because complying with the licensing requirement is costly and burdensome, and because that requirement is preempted, Taylor has given up his license. *Id.* at 5. As a consequence of the state's enforcement of the preempted regulations, he is forced to either give up his profession and the income it provides, or face prosecution for unlicensed hearing aid sales and fitting. *Id.* at 10.

In *Odebrecht*, 715 F.3d at 1288, the Eleventh Circuit affirmed a preliminary injunction on the basis that the plaintiff would be harmed by lost revenues and profits. There, a corporation challenged a Florida law that barred any company that does business in Cuba from bidding on public contracts. The plaintiff sought an injunction because if the law were enforced during the lawsuit, the company would have lost its ability to bid on various projects and forfeited its revenue stream. The company had no recourse against the government defendant because the Eleventh Amendment bars damages in federal court. *See also ABC Charters*, 591 F. Supp. 2d 1272 (loss of key component of business was actual and irreparable injury).

Similarly here, Taylor is faced with actual and imminent financial harm. He routinely receives requests from both past and new customers related to hearing aid sales.

Taylor Decl. at 11. Because he has been threatened with potential penalties and fines, he must decline those requests. *Id.* That harm is irreparable because sovereign immunity renders it impossible for him to recover damages from state officials in a future action. *ABC Charters*, 591 F. Supp. 2d 1272 (economic harm that cannot be recovered because of the Eleventh Amendment is "irreparable as a matter of law").

Taylor also is injured because he faces potential prosecution. Florida law prohibits the sale of hearing aids without a license, and subjects violators to significant penalties. Selling a hearing without a license is a felony, Fla. Stat. § 484.053, and is punishable by up to five years in prison. Defendants are currently investigating Taylor to determine whether he has violated the licensing law. This threat of criminal prosecution alone constitutes irreparable harm. *See ABC Charters*, 591 F. Supp. 2d 1272 ("[A]n individual who is imminently threatened with prosecution for conduct that he believes is constitutionally protected should not be forced to act at his peril.") (citation omitted).

In sum, Taylor faces lost business profits and potential criminal prosecution. Both harms are actual and imminent, as evidenced by Defendants' letter notifying him of a current investigation, and they are irreparable. A preliminary injunction is necessary to prevent these harms and to give Taylor a full opportunity to seek resolution of his claims in court.

III

THE BALANCE OF THE EQUITIES WEIGHS IN FAVOR OF GRANTING THE INJUNCTION, AND AN INJUNCTION IS NOT ADVERSE TO THE PUBLIC INTEREST

Taylor faces an immediate threat of substantial harm. Taylor Decl. at 10. That harm far outweighs any potential "injury" to the Defendants if the injunction is granted; the state is not harmed by being prevented from enforcing an unconstitutional law. *KH Outdoor*, 458 F.3d at 1272. And if the state is enjoined from enforcing its law, the public will be adequately protected by federal law, which already restricts the sale of hearing aids in a manner the FDA has deemed necessary to protect the public.

Granting the injunction promotes the public interest because the public interest does not support "[a] city's expenditure of time, money, and effort in attempting to enforce an ordinance that may well be held unconstitutional." *Florida Businessmen for Free Enterprise v. City of Hollywood*, 648 F.2d 956, 959 (5th Cir. 1981). Instead, the public has a substantial interest "in determining the constitutionality" of a challenged law. *ABC Charters*, 591 F. Supp. 2d at 1310. An injunction will allow Taylor to seek judicial resolution of his claims.

IV

BOND SHOULD BE WAIVED OR SET AT A NOMINAL AMOUNT

Federal Rule of Civil Procedure 65(c) requires that, before issuing an injunction, the Court require the movant to post a bond "in an amount that the court considers proper." The court also has discretion to issue the injunction without bond. *See, e.g.*, *Occupy Fort Myers v. City of Fort Myers*, 882 F. Supp. 2d 1320, 1339-40 (M.D. Fla. 2011) ("[I]t is well-

established that "the amount of security required by the rule is a matter within the discretion of the trial court . . . and the court may elect to require no security at all."). Courts routinely approve of dispensing with the bond requirement when an injunction is unlikely to result in substantial harm, where the exercise of constitutional rights is at issue, or when a suit is brought in the public interest. *See Moltan Co. v. Eagle-Picher Indus., Inc.*, 55 F.3d 1171, 1176 (6th Cir. 1995) and *Save Our Sonoran, Inc. v. Flowers*, 408 F.3d 1113, 1126 (9th Cir. 2005) ("[R]equiring nominal bonds is perfectly proper in public interest litigation."). *See also Occupy Fort Myers*, 882 F. Supp. 2d at 1340 (requiring a nominal $100 bond where an ordinance involving free speech rights was challenged as unconstitutional).

Preliminary relief is unlikely to harm the Defendants or the public. In all of his years as a licensed Hearing Aid Specialist, Taylor was never disciplined or sanctioned by the Board of Hearing Aid Specialists or any other administrative or law enforcement agency due to any consumer complaint. *Id.* ¶ 4. And federal law will protect the public even if Florida's law is enjoined during the lawsuit.

Requiring a bond, on the other hand, would significantly harm Taylor's ability to vindicate his constitutional rights and to pursue this case. Because of Defendants' enforcement of the challenged law, he is required to shutter his business and is deprived of revenue. He therefore has brought this civil rights lawsuit in the public interest under 42 U.S.C § 1983. Though Taylor is being represented pro bono by a nonprofit public interest law firm, he is financially unable to post a significant bond. He therefore respectfully request that the Federal Rule of Civil Procedure 65(c) bond requirement be either waived or set at a nominal amount.

CONCLUSION

Taylor respectfully requests that this Court issue the preliminary injunction and enjoin Defendants from enforcing Florida's licensing requirements, Fla. Stat. §§ 484.053, 484.0501, and 484.054.

DATED: June 8, 2018.

Respectfully submitted:

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this day, June 8, 2018, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all counsel of record.

s/ Anastasia P. Boden
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